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EXAMINER

PASS, NATALIE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/733,215 | Applicant(s) PRASAD ET AL. | |
| | Examiner Natalie A. Pass | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Notice to Applicant

1. This communication is in response to the amendment filed 3 December 2007. Claim 1 has been amended. Claims 16-33 have been cancelled. Grounds of rejection for claims 1-15 are presented in the instant application as set forth in detail below.

Claim Objections

2. The objection to claim 1 because of informalities is hereby withdrawn due to the amendment filed 3 December 2007.

Claim Rejections - 35 USC § 112

3. The rejection of claim 2 under the first paragraph of 35 U.S.C. §112, for containing new matter, is hereby withdrawn due to the amendment filed 3 December 2007.

4. The rejection of claim 1 under the second paragraph of 35 U.S.C. §112, as being indefinite, is hereby withdrawn due to the amendment filed 3 December 2007.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (2001/0020229 A1) and Trusheim, et al, U.S. Patent Number 6, 385, 589 for substantially the same reasons given in the previous Office Action (paper number 20070612), and further in view of Boyko, et al. (CA 2216681). Further reasons appear hereinbelow.

(A) Claim 1 has been amended to include the recitation of

- ♦ "the members having a plurality of diseases or health conditions," in line 4;
- ♦ "is calculated to enable comparison of the predicted future healthcare utilizations of members having different diseases or health conditions," in lines 8-9;
- ♦ "wherein the selected high-risk members have a plurality of diseases or health conditions," in lines 11-12; and
- ♦ "compiling a data set including all stored healthcare data associated with each selected high-risk member," in lines 13-14.

As per newly amended claim 1, Lash and Trusheim teach a method as analyzed and discussed in the previous Office Action (paper number 20070612), further comprising wherein the predicted future healthcare utilization for each of the plurality of members ... [...] ... is calculated to enable comparison of the predicted future healthcare utilizations of members (LASH; paragraphs [0007], [0055], [0048], page 8, claims 8, 12, 17); Examiner interprets Lashes teachings of "probability values for each patient which are indicative of the likelihood that the patient will acquire high service utilization characteristics. For instance, such high service use characteristics can include the patient suffering one or more high-cost medical events or episodes, or the patient becoming a high user of services overall relative to other

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patients” (Lash; paragraph [0007]) and of comparing a score with a threshold for each of the members (LASH; paragraph [0055]) and of calculating average probabilities and applying a probability equation to each patient record (LASH; claim 12) as teaching a form of “calculated to enable comparison of the predicted future healthcare utilizations of members;” and

compiling a “subset” (reads on “data set”) including all stored healthcare data associated with each selected high-risk member (Lash; paragraphs [0007], [0022]).

Lash and Trusheim fail to explicitly disclose

the members having a plurality of diseases or health conditions; and

wherein the selected high-risk members have a plurality of diseases or health conditions.

However, the above features are well-known in the art, as evidenced by Boyko.

In particular, Boyko teaches a method further including

the members having a plurality of diseases or health conditions (Boyko; page 5, lines 9-15); and

wherein the selected high-risk members have a plurality of diseases or health conditions (Boyko; page 5, lines 9-15, page 10, lines 3-9); Examiner interprets Boyko’s teaching of “multiple diseases or conditions can be factored into a single analysis and thereby develop a risk profile based on multiple factors and multiple diseases or conditions” (Boyko; page 5, lines 9-15), together with Boyko’s teachings of “applies a statistical predictive model and rules to patient data from the Disease Management 5 database 120 corresponding to a group of patients selected from the Disease Management database 120 based on a predetermined criteria” (Boyko; page 10, lines 3-9) to teach a form of “the members having a plurality of diseases or health

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conditions” and “selecting one or more high-risk members ... [...] ... wherein the selected high-risk members have a plurality of diseases or health conditions.”

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combined teachings of LASH and Trusheim to include these limitations, as taught by Boyko, with the motivations of reducing “the total costs of treating the whole population” by providing “identification of high-risk patients for disease and providing disease intervention management using various electronic computational processing techniques” (Boyko; page 1, paragraph 1-4).

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action (paper number 20070612, section 11, pages 6-9), and incorporated herein.

The motivations for combining the respective teachings of Lash and Trusheim are as given in the rejection of claim 1 in the prior Office Action (paper number 20070612) and incorporated herein.

(B) Claims 2-11 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 20070612, section 11, pages 9-12), and incorporated herein.

7. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (2001/0020229 A1), Trusheim, et al, U.S. Patent Number 6, 385, 589, and Boyko, et al. (CA 2216681), as applied to claim 1 above and further in view of Lutgen et al. (US 2003/0167189A1) for substantially the same reasons given in the previous Office Action (paper number 20070612). Further reasons appear hereinbelow.

(A) Claims 12-13 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 20070612, section 12, pages 15-16), and incorporated herein.

8. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (US2001/0020229 A1), Trusheim, et al, U.S. Patent Number 6, 385, 589, Boyko, et al. (CA 2216681) and Lutgen et al. (US 2003/0167189A1), as applied to claims 1 and 12 above, and further in view of Lockwood et al. U.S. Patent Number 5, 845, 254 for substantially the same reasons given in the previous Office Action (paper number 20070612). Further reasons appear hereinbelow.

(A) Claims 14-15 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 20070612, section 13, pages 17-18), and incorporated herein.

Response to Arguments

9. Applicant's arguments filed 3 December 2007 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3 December 2007.

(A) At pages 6, paragraph 4 of the 3 December 2007 response Applicant argues the rejection of claim 2 under 35 U.S.C. §112, first paragraph for reciting limitations that are new matter, and points out support for the rejected limitations in the specification. Applicant's

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argument is persuasive. Examiner thanks Applicant for this explanation, and has withdrawn the rejection.

(B) At pages 7-13 and 15-16 of the 3 December 2007 response Applicant argues that the features in recited claims 1-15 are not taught or suggested by the applied references. These arguments have been considered but are moot in view of the new ground(s) of rejection.

(C) At pages 14-15 of the 3 December 2007 response Applicant argues that there is no suggestion to combine the references. Examiner respectfully disagrees. In response to Applicant's argument, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Also see *Teleflex Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282, 288 (Fed. Cir. 2005).

Furthermore, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. And although the motivation or suggestion to make modifications must be articulated, it is respectfully submitted that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that the Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re Delisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)); and *Teleflex Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282, 288 (Fed. Cir. 2005). Further, it was determined in *In re Lamberti et al* 192 USPQ 278 (CCPA) that:

- (i) obvious does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not express teaching of references but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. In *In re Conrad* 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references is accompanied by select portions of the respective reference(s) which specifically support that particular motivation. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one

ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood* 28 USPQ 2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

In addition, Examiner notes that Lash teaches “an automated data processing system for predicting the likelihood that a patient will acquire high service utilization characteristics, thereby becoming more of a high-cost patient to a managed care organization or the like, than other patients” and analyzes a “subset of ... [...] ... claims data ... [...] ... selected based on the results of multivariate statistical regression modeling which selects high relevance claims variables from the potential claims variables to predict whether a patient will acquire high-use characteristics” (Lash; paragraph [0007]).

Lash teaches targeting high use patients for intervention (Lash; Abstract) but does not teach searching the stored healthcare data associated with each selected high-risk member to identify the presence of at least one intervention flag for the member, wherein each intervention flag corresponds to a member attribute amenable to intervention and generating an output including the at least one intervention flag and the claim data associated with each member in the intervention group.

Trusheim teaches a “system ... [...] ... in which member characteristics of a member are identified, a list of the member characteristics are stored, information indicative of a medical event is continuously monitored, information indicative of a medical event is obtained, and a risk situation is automatically identified based on the member characteristics and the medical event information,” (Trusheim; column 3, lines 55-62) and “in which member characteristics of each member of a patient population are determined from member surveys, care providers, insurance

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claim data, historical health care data or the like, and medical events are periodically detected from laboratory data, pharmacy benefits manager data, hospital data, physician records, home health care data, direct conversations with members and physicians, health plan data or other sources,” (Trusheim; column 4, lines 4-11). Trusheim also teaches searching the stored healthcare data associated with each selected high-risk member (Trusheim; Figure 29, Figure 30, column 3, line 55 to column 4, line 11, column 14, lines 59-66, column 15, line 54 to column 16, line 12, column 19, lines 46-60) to identify the presence of at least one intervention “code” (reads on “flag”) for the member, wherein each intervention “code” (reads on “flag”) corresponds to a member attribute amenable to intervention (Trusheim; Figure 32, column 2, lines 46-60, column 5, lines 20-29, column 11, lines 10-17, 27-40, column 12, lines 8-11), and generating an output including the at least one intervention flag and the claim data associated with each member in the intervention group (Trusheim; Figure 29, Figure 30, Figure 32, column 21, lines 16-18, column 21, line 64 to column 22, line 10).

Lash fails to teach the members having a plurality of diseases or health conditions.

Boyko teaches a predictive health outcome modeling process that produces a statistical model used to predict whether a patient with a particular disease is likely to suffer an adverse health outcome (Boyko; Abstract) in which “multiple diseases or conditions can be factored into a single analysis and thereby develop a risk profile based on multiple factors and multiple diseases or conditions,” (Boyko; page 5, lines 9-15).

Since each individual element and its function are shown in the prior art, albeit shown in separate references, the difference between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself - that is in the

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substitution of the “intervention flag” of the secondary reference(s) for the identification methodology that identifies when intervention is necessary of the primary reference and in the substitution of the statistical analysis of predicted future healthcare utilizations of members having a plurality of medical conditions of the tertiary reference(s) for the analysis of predicted future healthcare utilizations of members having a particular medical condition of the primary reference . Thus, the simple substitution of one known element for another producing a predictable result renders the claim obvious. (See *Teleflex Inc. v. KSR Int’l Co.*, 119 Fed. Appx. 282, 288 (Fed. Cir. 2005).

As such, it is respectfully submitted that Applicant appears to view the applied references separately, without considering the knowledge of average skill in the art, and further fails to appreciate the breadth of the claim language that is presently recited.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. **Any response to this final action should be mailed to:**

Box AF

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: (571) 273-8300.

For formal communications, please mark

"EXPEDITED PROCEDURE".

For informal or draft communications, please label

"PROPOSED" or "DRAFT" on the front page of the

communication and do NOT sign the communication.

After Final communications should be labeled "Box AF."

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NAP/

Examiner, Art Unit 3626

February 18, 2008

/C. Luke Gilligan/

Primary Examiner, Art Unit 3626